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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,328	12/07/1999	KUBER T. SAMPATH	CIBT-P01-514	9813
28120	7590	10/20/2003	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			ROMEO, DAVID S	
			ART UNIT	PAPER NUMBER

1647

DATE MAILED: 10/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/445,328

Applicant(s)

SAMPATH ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2,5,6 and 8-38 is/are pending in the application.
- 4a) Of the above claim(s) 21,22,25,26 and 28-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,5,6,8-20,23,24,27 and 35-38 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☒ Claim(s) 2,5,6 and 8-38 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

The amendment filed June 16, 2003 has been entered. Claims 2, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38 are pending. Applicant's election with traverse of Group X, the species OP-1, the species the mature form of OP-1, the species pre-renal causes of acute renal failure, the species decreased cardiac output, and the species intravenous administration in Paper No. 12 is acknowledged. Claims 21, 22, 25, 26, 28-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12. Claims 2, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38 are being examined only to the extent they read upon the elected invention and/or species.

15 **Maintained Formal Matters, Objections, and/or Rejections:**

***Claim Rejections - 35 USC § 103***

Claims 2, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 24, 27, 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuberasampath (AH) in view of Anderson (u14).

20 Applicant argues that the examiner had not rejected claim 7, and that claim 2 has been amended to incorporate the limitations of claim 7. Applicant's arguments have been fully considered but they are not persuasive. It was not previously necessary to reject claim 7 in this rejection, because claim 7 was previously rejected in another rejection.

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Furthermore, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention because there has been an increasing tendency to use dialysis therapy early in acute renal failure, and insofar as impaired cardiac output is a major cause of acute deterioration in renal function and there has been an increasing

5 tendency to use dialysis therapy early in acute renal failure, and insofar as kidney malfunction causes a calcium and phosphate imbalance in the blood, particularly those requiring dialysis, and cause or result in bone fractures or other defects in skeletal microstructure, including loss of bone mass, and which compromise the weight-bearing capacity of bone, and to the extent that these defects in skeletal microstructure, including

10 loss of bone mass, which compromises the weight-bearing capacity of bone, can be treated by the administration of OP-1, then it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to administer OP-1 to a mammal afflicted with acute renal failure, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification in order to prevent

15 loss of bone mass and/or increase bone mass in the mammal with kidney disease or renal malfunction. The invention is prima facie obvious over the prior art.

Claims 2, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuberasampath (AH, cited by Applicants) in view of Anderson (u14) as applied to claim

20 2 above, and further in view of Spragg (a14), Saavedra (b14), and Kuberasampath (AG, cited by Applicants).

To the extent Applicant argues that the examiner had not rejected claim 7, and that claim 2 has been amended to incorporate the limitations of claim 7. Applicant's

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arguments have been fully considered but they are not persuasive. It was not previously necessary to reject claim 7 in this rejection, because claim 7 was previously rejected in another rejection.

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***Claim Rejections - 35 USC § 112***

Claims 2, 8-20, 23, 24, 27, 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treatment comprising administering OP-1 to a mammal, does not reasonably provide enablement for a method of treatment comprising administering the other OP/BMP renal therapeutic agents recited in the claims.

Applicant argues that the claims are enabled. Applicant's arguments have been fully considered but they are not persuasive. The present claims are not directed to a method of regulating dendritic growth. The only working examples in the specification are with OP-1. There are no working examples of other OP/BMP renal therapeutic agents. Other than claim 13, the claims do not recite a clear functional limitation to the OP/BMP renal therapeutic agents. The specification provides no guidance as to which of the myriad of structural embodiments are more likely than not to function in the manner disclosed. The skilled artisan is left to extensive experimentation wherein OP/BMP renal therapeutic agents are randomly made and through trial and error experimentation is left to determine how to achieve the desired results. It is suggested that claim 2 be amended to include a functional limitation for the agent.

**New Formal Matters, Objections, and/or Rejections:**

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*Claim Objections*

Claim 5 is objected to because of the following informalities: "BMPS" should be "BMP5". Appropriate correction is required.

*Conclusion*

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHT FAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHT FAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

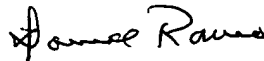
CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

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DSR  
OCTOBER 19, 2003